

PDB10

A CROSS-OVER RANDOMISED CONTROLLED TRIAL TO COMPARE PSYCHOLOGICAL BARRIERS TO INSULIN SELF-INJECTION WITH THE INNOLET AND VIAL/SYRINGE

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OBJECTIVES: The timely initiation of insulin therapy in patients with type-2 diabetes who fail to achieve good control on oral antidiabetic therapy is pivotal to successful health outcomes in diabetes. Yet, significant barriers exist to patient acceptance of insulin therapy and to adequate self-management of insulin regimens once initiated. The disposable insulin device, InnoLet, is designed to meet the needs of elderly patients. This study set out to evaluate the differences in psychological fear of self-injecting insulin and perception of barriers to compliance with the insulin regimen in patients using the InnoLet pre-filled device and the vial and syringe. **METHODS:** Eighty diabetes patients >60 years of age and having visual and or motor disabilities were enrolled in this two-period crossover study, which had as primary aim to evaluate resource utilisation and patient preference. Subjects had difficulty or required caregiver assistance for their previous regimen of injections by vial/syringe. Subjects were randomised to use of either vial and syringe or InnoLet for 6 weeks, and then assigned the opposite treatment for six weeks. At baseline and at the end of each period, subjects completed the Diabetes Fear of Self-injection Questionnaire (D-FISQ) and questions about barriers to insulin self-care, treatment satisfaction and preference. **RESULTS:** The D-FISQ showed good internal consistency. Compared to baseline values, InnoLet treatment resulted in an improvement of 39% and 67% respectively in each of the 2 groups in fear of self-injection, whereas vial-syringe treatment resulted in small improvements of 4,7% and 17% respectively from baseline. Detailed statistical analyses of the relationships between injection fear, treatment barriers and health care utilisation further demonstrate the clinical importance of injection fear. **CONCLUSION:** The pre-filled InnoLet device offers important psychological benefits to elderly insulin dependent diabetes patients with visual and or motor disabilities. The clinical significance of these findings is substantial, given the significant health gains that can be obtained with effective insulin therapy.

PDB11

TYPE I DIABETES, LONG-TERM COMPLICATIONS AND QUALITY OF LIFE MEASURED WITH RAND-36 HEALTH PROFILE MEASURE

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OBJECTIVES: Profile measures of health-related quality of life (HRQoL) are not adequate for all purposes in health economics, but when the effects of a disease or medical treatment to some specific domain of health are considered, profile measures can provide results that are illustrative and easy to interpret. In this study we examine how the effects of type 1 diabetes (T1D) and the symptoms of its chronic long-term complications affect the hypothesized physical and mental domains of HRQoL. **METHODS:** A representative sample of patients with T1D was selected randomly from the Finnish drug reimbursement registry. Patients then reported symptoms, diagnoses, and treatments indicating time of appearance and presence of long-term complications, and filled RAND-36 questionnaire. An explorative factor analysis was performed to test the hypothesis of 2-factor model of health. The results were validated with split-sample analysis. Regression analyses were used in estimating the effects of age, gender and symptoms of long-term complications to the factor component T-scores. **RESULTS:** Of the 752 (70.8%) patients who responded, 592 were with T1D and 96.2% completed the RAND-36 questionnaire. Factor analysis of our data supports the theory of the 2-factor model of health; physical and mental health components were reflected unambiguously by different RAND-36 dimensions. The regression results show that the symptoms of long-term complications influence much stronger on physical than mental domain of the HRQoL. The number of significant symptoms was higher in physical component model (5/8 vs. 3/8) and the coefficient values of those were higher (3.1–4.4 vs. 2.3–3.7). **CONCLUSIONS:** T1D and especially the symptoms of its long-term complications affect mainly the physical domain of health, although the mental domain is also affected. The prevalence of long-term complications of T1D in different age groups is sufficiently high to substantially influence on the quality of life of the patients.

PDB12

SELF-ASSESSMENT OF DIABETES CONTROL: ACCURACY OF PATIENTS' PERCEPTIONS

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OBJECTIVE: To determine the accuracy of self-reported glucose levels among people with diabetes. **METHODS:** In August 1999, 903 people with diabetes were sent an at-home HbA1c test kit and a brief questionnaire about blood glucose monitoring and diabetes management. The sample was obtained through an on-going, longitudinal diabetes study. A total of 450 respondents provided a self-reported range of blood glucose levels and completed the home test kit. The midpoint and highest glucose level were compared to laboratory HbA1c values using a regression equation calculated from a previously published formula. The percentage of respondents misestimating their diabetes control was determined. **RESULTS:**